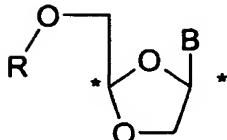


What is claimed is

1. A pharmaceutical combination comprising at least one active compound of formula (I):

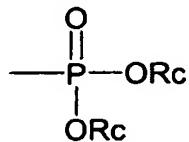
5



(I)

~ Troxaly<sup>TM</sup>  
troxacitabine

or a pharmaceutically acceptable salt thereof, *open*  
wherein B is cytosine or 5-fluorocytosine and R is selected  
10 from the group comprising H, monophosphate, diphosphate,  
triphosphate, carbonyl substituted with a C<sub>1-6</sub> alkyl, C<sub>2-6</sub>  
alkenyl, C<sub>2-6</sub> alkynyl, C<sub>6-10</sub> aryl and



wherein each R<sub>c</sub> is independently selected from the group  
15 comprising H, C<sub>1-6</sub> alkyl, C<sub>2-6</sub> alkenyl, C<sub>2-6</sub> alkynyl and a hydroxy  
protecting group;

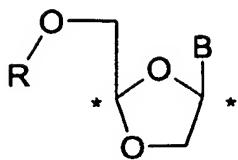
and a Bcr-Abl tyrosine kinase inhibitor.

20 2. The pharmaceutical combination according to claim 1, wherein  
the Bcr-Abl tyrosine kinase inhibitor is imatinib mesylate (STI-  
571).

25 3. The pharmaceutical combination according to claim 2,  
wherein R is H.

4. The pharmaceutical combination according to claim 2,  
wherein B is cytosine.

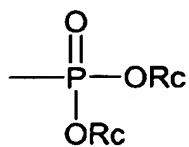
5. The pharmaceutical combination according to claim 2, wherein R is H and B is cytosine.
6. The pharmaceutical combination according to claim 2, wherein B is 5-fluorocytosine.
- 5 7. The pharmaceutical combination according to claim 2, wherein the compound of formula I is (-)- $\beta$ -L-Dioxolane-Cytidine ( $\beta$ -L-OddC).
- 10 8. The pharmaceutical combination according to Claim 2, wherein the compound of formula I is (-)- $\beta$ -Dioxolane-5-fluoro-Cytidine (5-FddC).
9. The pharmaceutical combination according to claim 2, wherein the compound of formula I is substantially in the form of the (-) enantiomer.
- 15 10. The pharmaceutical combination according to claim 2, wherein said compound of formula (I) is at least 97% free of the corresponding (+) enantiomer.
11. The pharmaceutical combination according to claim 2 wherein the compound of formula (I) is  $\beta$ -L-OddC and the Bcr-Abl tyrosine kinase inhibitor is imatinib mesylate (STI-571).
- 20 12. A pharmaceutical combination according to claim 2 wherein the compound of formula (I) and imatinib mesylate (STI-571) are present in a ratio between about 1:50 to about 50:1.
- 25 13. A pharmaceutical combination according to claim 2 wherein the compound of formula (I) and imatinib mesylate (STI-571) are present in a ratio between about 1:20 to about 20:1.
- 30 14. A pharmaceutical combination comprising at least one active compound of formula (I):



(I)

or a pharmaceutically acceptable salt thereof,

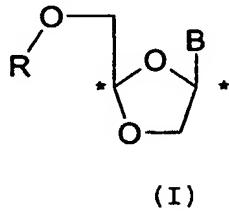
wherein B is cytosine or 5-fluorocytosine and R is selected  
5 from the group comprising H, monophosphate, diphosphate,  
triphosphate, carbonyl substituted with a C<sub>1-6</sub> alkyl, C<sub>2-6</sub>  
alkenyl, C<sub>2-6</sub> alkynyl, C<sub>6-10</sub> aryl and



wherein each Rc is independently selected from the group  
10 comprising H, C<sub>1-6</sub> alkyl, C<sub>2-6</sub> alkenyl, C<sub>2-6</sub> alkynyl and a hydroxy  
protecting group;

and a Bcr-Abl tyrosine kinase inhibitor and the compound of  
formula (I) and the Bcr-Abl tyrosine kinase inhibitor are  
present in a synergistic ratio.

15 15. A method of treating a patient having leukemia  
comprising administering to said patient a therapeutically  
effective amount of a compound of formula I:

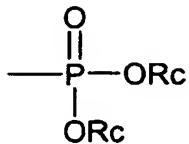


acute myelogenous  
leukemia;  
chronic myelogenous  
leukemia;  
acute lymphocytic  
leukemia;

or a pharmaceutically acceptable salt thereof, *acute lymphocytic leukemia*;

20 wherein B is cytosine or 5-fluorocytosine and R is selected  
from the group comprising H, monophosphate, diphosphate,  
triphosphate, carbonyl substituted with a C<sub>1-6</sub> alkyl, C<sub>2-6</sub>  
alkenyl, C<sub>2-6</sub> alkynyl, C<sub>6-10</sub> aryl and

chronic lymphocytic  
leukemia;  
hairy cell  
leukemia



wherein each  $\text{Rc}$  is independently selected from the group comprising  $\text{H}$ ,  $\text{C}_{1-6}$  alkyl,  $\text{C}_{2-6}$  alkenyl,  $\text{C}_{2-6}$  alkynyl and a hydroxy protecting group;

5 and Bcr-Abl tyrosine kinase inhibitor.

16. A method of treating a patient having leukemia according to claim 15 and wherein the ratio of the compound 10 of formula (I) and the Bcr-Abl tyrosine kinase inhibitor is 1:250 to 250:1.

17. The method according to claim 15, wherein the step of administering comprises administering to a patient with 15 acute myelogenous leukemia and chronic myelogenous leukemia.

18. The method according to claim 15, wherein the step of administering comprises administering to a patient with chronic myelogenous leukemia in blastic phase.

20 19. The method according to claim 15, wherein the step of administering comprises administering to a patient with refractory / relapsed leukemia.

25 20. The method according to claim 15, wherein the step of administering comprises administering to a patient with refractory / relapsed leukemia and which has been previously treated with imatinib mesylate (STI-571).

21. The method according to claim 15, wherein the step of administering comprises administering to a patient with refractory / relapsed leukemia and which has been 30 previously treated with imatinib mesylate (STI-571) and is resistant to imatinib mesylate (STI-571).

22. The method according to claim 15, wherein the step of administering comprises administering to a patient with refractory / relapsed leukemia and which has been previously treated with imatinib mesylate (STI-571) wherein the compound of formula (I) is  $\beta$ -L-OddC and the Bcr-Abl tyrosine kinase inhibitor is imatinib mesylate (STI-571).

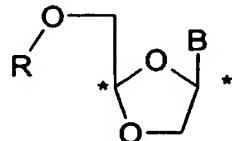
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23. The method according to claim 15, wherein the step of administering comprises administering to a patient with refractory / relapsed leukemia and which has been previously treated with imatinib mesylate (STI-571) and wherein the compound of formula (I) is  $\beta$ -L-OddC and the Bcr-Abl tyrosine kinase inhibitor is imatinib mesylate (STI-571) and said combination is a synergistic combination.

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24. A method of treating a patient having cancer, other than leukemia, comprising administering to said patient a therapeutically effective amount of a compound of formula I:

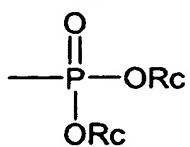
15



(I)

or a pharmaceutically acceptable salt thereof,

20 wherein B is cytosine or 5-fluorocytosine and R is selected from the group comprising H, monophosphate, diphosphate, triphosphate, carbonyl substituted with a  $C_{1-6}$  alkyl,  $C_{2-6}$  alkenyl,  $C_{2-6}$  alkynyl,  $C_{6-10}$  aryl and



25 wherein each Rc is independently selected from the group comprising H,  $C_{1-6}$  alkyl,  $C_{2-6}$  alkenyl,  $C_{2-6}$  alkynyl and a hydroxy protecting group;

and a Bcr-Abl tyrosine kinase inhibitor;

and at least one further therapeutic agent chosen from a nucleoside analogue and/or a chemotherapeutic agent.

5

25. A pharmaceutical composition comprising a pharmaceutical combination according to claim 1 and at least one pharmaceutically acceptable carrier or excipient.

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